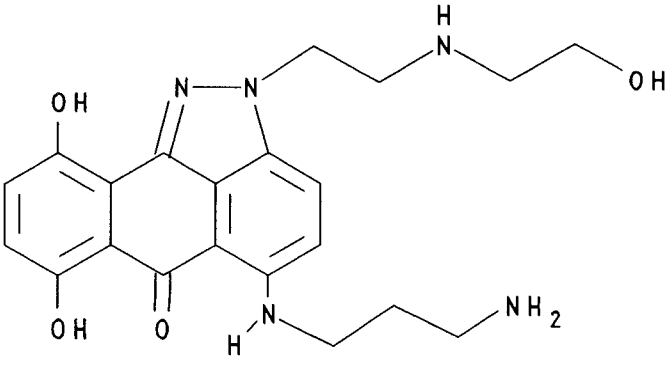
PIROXANTRONE

NSC - 349174



Chemical Name: 5-[(3-Aminopropyl)amino]-7,10-dihydroxy-2-[2-[(2-hydroxyethyl)amino]ethyl]-anthra[1,9-cd]-pyrazol-6(2H)-one, dihydrochloride

Other Names: Oxantrazole Hydrochloride; Anthrapyrazole Dihydrochloride, Piroxantrone Hydrochloride (USAN)

CAS Registry Number: 105118-12-5

Molecular Formula: $C_{21}H_{25}N_5O_4 \cdot 2HCl$ **M.W.:** 484.4

How Supplied: For Injection, 50 mg, vial: supplied as a deep red lyophilized powder with 50 mg of mannitol, USP, in a 10 mL flint vial.

Solution Preparation: 50 mg/vial: When constituted with 2.5 mL of Sterile Water for Injection, USP, each milliliter contains 20 mg of piroxantrone HCl and 20 mg of mannitol, USP, at pH 4 to 6.

Storage: Store the intact vials in the freezer (-10 to -20 °C).

Stability: Shelf-life surveillance of the intact vials is ongoing. One lot has maintained stability for at least 36 months at room temperature (22-25 °C). The intact vials were unstable at elevated temperature (50 °C).

Solutions of piroxantrone HCl are most stable below pH 6. A study of piroxantrone HCl at pH values from 3.4 to 8.0 in various buffer systems at 70 °C yielded the following half-life results:

pH	**Approx. $t_{1/2}$ (70 °C)**
8.0	5 min.
7.3	18 min.
6.4	2 hr.
5.6	7 hr.
4.5	32 hr.
3.4	41 hr.

Constitution as recommended results in a solution which is chemically stable for 14 days under refrigeration, at room temperature, and at 37 °C.

Further dilution to a concentration of 0.1 mg/mL in 0.9% Sodium Chloride Injection, USP, and 5% Dextrose Injection, USP, in glass bottles and plastic bags yielded the following results:

Percentage Piroxantrone HCl[a]
Remaining In Infusion Solutions

Diluent	Temp. (°C)	Days 1	2	3	4
NS[b]	37	98	95	93	85
	25	99	99	98	90
	4	100	100	100	100
D5W[c]	37	100	100	100	96
	25	100	100	100	96
	4	100	100	100	100

(a) Initial concentration 0.1 mg/mL
(b) 0.9% Sodium Chloride Injection, USP
(c) 5% Dextrose Injection, USP

CAUTION: The single-use lyophilized dosage form contains no antibacterial preservatives. Therefore, it is advised that the constituted product be discarded within 8 hours of initial entry.

Route of Administration: Intravenous